UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MELANIE STACEL	)	
	)	
Plaintiff,	)	
	)	Case No. 08 C 1143
v.	)	
	)	Judge Joan B. Gottschall
TEVA PHARMACEUTICALS, USA, et al.	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

BACKGROUND

Plaintiff Melanie Stacel brought suit in the Circuit Court of Cook County against Defendant Teva Pharmaceuticals, USA ("Teva"), which Teva removed to this court on the basis of diversity jurisdiction. The suit involves Stacel's allegation that she was afflicted with drug-induced lupus as a result of consuming the drug minocycline, which is a generic of the brand-name, FDA reference-listed drug Minocin®. Minocycline is manufactured by Teva. Stacel presents four counts, including a products liability claim on the theory of negligent failure to warn (Count I); a common-law fraud and misrepresentation claim (Count II); a claim based on the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA") (Count III), and a claim for punitive damages (Count IV).

Teva has moved to dismiss, arguing that Counts II and III should be dismissed because they do not satisfy the heightened pleading standard of Rule 9(b) of the Federal Rules of Civil Procedure. Teva also argues that the entire complaint should be dismissed because Stacel's state-law causes of action are preempted by the federal Food, Drug and Cosmetic Act ("FDCA"). For purposes of this motion, all allegations in Stacel's complaint are accepted as true, and all reasonable inferences are drawn in favor of the plaintiff. *INEOS Polymers Inc. v. BASF Catalysts*, 553 F.3d 491, 497 (7th

Cir. 2009). A motion to dismiss will be denied so long as the complaint states a legal claim upon which relief can be granted. *Id.*

ANALYSIS

I. Heightened Pleading

Rule 9 states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To comply, the plaintiff must (1) state the identity of the person or entity who made the misrepresentation, (2) state the time, place and content of the misrepresentation, and (3) state the method by which the misrepresentation was communicated to the plaintiff. *Vicom, Inc. v. Harbridge Merchant Serv. Inc.*, 20 F.3d 771, 777 (7th Cir. 1994). Put more succinctly, the plaintiff must plead the who, what, when, where, and how of the fraud. *Siegel v. Shell Oil Co.*, 480 F. Supp. 2d 1034, 1043 (N.D. Ill. 2007).

Teva contends that Counts II and III "do[] not even come close to pleading these claims with sufficient particularity." Mem. in Supp. of Mot. to Dismiss 2 (Doc. No. 23) ("Mot. to Dismiss"). Teva does not take issue with the identity requirement, but does take issue with the amount of specificity needed regarding the alleged misrepresentation. Stacel alleges that Teva concealed its full knowledge that minocycline may cause lupus, but Teva argues that Stacel has not provided any specific showing that Teva in fact had such a knowledge. Mot. to Dismiss 4. Teva also argues that the time, place, content, and method requirements are not satisfied. Teva concedes that Stacel has alleged that the misrepresentation regards a lack of notice of the risk of drug-induced lupus in the drug's labeling, but faults Stacel for failing to "attach a copy" of the faulty labeling, or to specifically identify "the purported 'fraudulent' language." *Id.*

Teva demands more than Rule 9 requires. Rule 9 does not require Stacel to attach a physical specimen of the allegedly faulty labeling. Rather, she must provide the who, what, when, where,

and how of her fraud claim. This she has done. Stacel is alleging that Teva ("who") has misrepresented the risk that minocycline poses for drug-induced lupus ("what") by failing to include a warning about this risk in its package labeling ("how"). She has alleged "when"—during the period that she allegedly consumed minocycline—and "where"—in the drug's labeling. This is all that Stacel is obligated to do at this stage of the litigation.[1]

Teva also challenges Stacel's compliance with the particular pleading requirements of the ICFA in Stacel's third count. To state an ICFA claim, Stacel must allege (1) a deceptive act or practice by Teva, (2) Teva's intent that Stacel rely on the deception, (3) that the deception occurred in the course of conduct involving trade and commerce, and (4) that the deceptive act proximately caused Stacel's injury. *See Cozzi Iron & Metal, Inc. v. U.S. Office Equip. Inc.*, 250 F.3d 570, 575–76 (7th Cir. 2001). Teva's arguments here repeat those raised regarding the requirements of Rule 9(b). Stacel's complaint alleges that Teva deceptively withheld information that minocycline might cause drug-induced lupus, that Teva did so with the intent that consumers like Stacel would rely on this deception, that the deception occurred in the course of commerce, and that the deception was the proximate cause of Stacel's injury. Stacel has satisfied these requirements.[2]

II. Preemption

Teva alternatively argues that Stacel's state-law claims are preempted by the labeling requirements of the FDCA. Federal preemption comes in three forms. The first is explicit

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[1] Teva could have attached the labeling to its motion to dismiss if it thought the labeling might be helpful to this court. *See 188 LLC v. Trinity Indus., Inc.*, 300 F.3d 730, 735 (7th Cir. 2002) (noting that documents referenced in complaint may be considered on a Rule 12(b)(6) motion to dismiss, if attached to motion to dismiss). Teva did not do so, and the court must assume at this stage that the complaint's factual characterization of the labeling's omissions is correct.

[2] Teva also argues that Stacel's claims that Teva failed to report cases of drug-induced lupus to the FDA lack specificity. *See* Mot. to Dismiss at 4, 6; 2d Am. Compl. ¶ 22(h) (Doc. No. 17). Teva's motion to dismiss on this basis is denied.

preemption stated in the federal statute. *English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990) ("First, Congress can define explicitly the extent to which its enactments pre-empt state law.") (citations omitted). The second is implied field preemption, which can "be inferred from a 'scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it,' or where an Act of Congress 'touches a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Id.* at 79 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)) (alterations in original). The third is implied conflict preemption, where "state law is pre-empted to the extent that it actually conflicts with federal law." *Id.* "Thus, the Court has found preemption where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (citations omitted). However, "the purpose of Congress is the ultimate touchstone in every preemption case," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotation marks omitted), and the court must "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172, at *5 (U.S. Mar. 4, 2009) (citations omitted). Teva argues that conflict preemption is appropriate here, because Teva cannot comply with both the FDCA's labeling requirements and the labeling requirements of Illinois state law, or that Illinois' torts law would frustrate the purpose and intent of Congress.[3]

[3] Stacel argues that Teva's preemption argument is premature because it cannot be known prior to discovery whether Teva has complied with federal law. This argument is in error. Teva is not arguing that its compliance with federal law should serve as a defense—it is arguing that federal law preempts any and all state law claims. *See Wyeth v. Levine*, No. 06-1249, 2009 WL 529172, at *5 (U.S. Mar. 4, 2009) (noting that because in that case the lower state court had not recommended a *particular* new label warning, which arguably might be rejected by the FDA, the Supreme Court was not deciding "whether a state rule proscribing intravenous administration would

The merits of Teva's argument requires a review of the regulatory scheme that drug manufacturers must navigate in order to obtain FDA approval, which is required before the drugs can be brought to market. *See Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612–13 (1973). Two schemes are relevant. The first relates to "new" or "reference-listed" drugs. The second is an abbreviated scheme that relates to "generic" drugs that are pharmaceutically equivalent to a reference-listed drug that the FDA has already approved. The drug at issue in this case—minocycline—is a generic drug.

Manufacturers of new drugs must submit a new drug application ("NDA") to the FDA, which includes information demonstrating the drug's effectiveness and safety for its intended use. *See* Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17950 (1992) (describing the NDA process). The FDA codified NDA regulations at 21 C.F.R. Part 314. As part of this process, drug manufacturers must include a proposed labeling for the drug, which the FDA can approve or reject. *See* 21 U.S.C. § 355; 21 C.F.R. § 314.105(b). After the FDA signs off on the drug and its label, the manufacturer must generally use the exact labeling that the FDA approved. *Id.* However, in limited circumstances the manufacturer may change the labeling after providing the FDA with notice of the change, but prior to actual FDA approval of the change. 21 C.F.R. § 314.70(c). This section, referred to as the "change being effected" ("CBE") provision, may be utilized only to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." §§ 314.70(c)(6)(iii)(A), (C). Manufacturers and consumer advocates have hotly litigated the issue of whether this labeling scheme preempts all state-law tort claims that might conclude that

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be preempted. The narrower question presented is whether federal law preempts [Plaintiff's] claim that [Defendant's] label did not contain an adequate warning . . . ."). This being a matter of law, it is properly decided at the motion to dismiss stage.

existing labeling is insufficient. The Supreme Court recently ruled that, in the context of new drugs, state-law claims are not preempted. *Levine*, 2009 WL 529172.

The Court's analysis in *Levine* is not directly controlling law since *Levine* dealt with a new drug manufacturer, whereas Teva is a generic drug manufacturer.[4] However, key parts of its analysis are applicable. First, the Court noted that when Congress amended the FDCA in 1982 to expand the FDA's powers to protect the public health and to assure the safety, effectiveness, and reliability of drugs, Congress expressly found that state-law claims should not be preempted except for incidents of "direct and positive conflict" with the FDCA. *Levine*, 2009 WL 529172 at *6 (citations omitted). Subsequent amendments continued to affirm this position. *See id.* at *6–*7. "[T]hrough many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulations that the manufacturer bears responsibility for the content of its label at all times." *Id.* at *8. Manufacturers are "charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* (citing, *inter alia*, 21 C.F.R. § 201.80(e), which requires manufacturers to revise labels to include additional warning information "as soon as there is reasonable evidence of an association of a serious hazard with a drug"). Although the FDA could subsequently reject the amended label, *see id.* at *9, the Court was unpersuaded by the argument that manufacturers ran the risk of being accused of having "misbranded" their products by utilizing the CBE process. The Court first noted its skepticism that adding an additional warning would constitute misbranding, and further observed that "the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulations is difficult to accept—neither [the manufacturer] nor the United

[4] As to generic manufacturers, the court is aware of no direct precedent, though further examination of this issue is anticipated in the wake of *Levine*.

States [as *amicus* in support of the manufacturer] has identified a case in which the FDA has done so." *Id.* at *8. The Court also observed that the manufacturer's argument would leave injured parties with no remedy, for injured parties have no cause of action under the FDCA. *Id.* at *10. Although Congress has the authority to eliminate certain remedies if it chooses to do so, the Court concluded that there was no evidence that this is what Congress intended—to the contrary, the Court assumed that Congress "determined that widely available state rights of action provide[] appropriate relief for injured consumers." *Id.* Congress was aware of state tort remedies, and chose not to foreclose them. *Id.*. "Its silence on the issue, coupled with its certain awareness of the procedure of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.*

The approval process for generic drug producers is similar but not identical to that for reference-listed drug producers. In 1984, Congress adopted the Drug Price Competition and Patent Term Restoration Act, known also as the Hatch-Waxman Act. Pursuant to this bill, the FDA implemented an abbreviated new drug application procedure ("ANDA") for manufacturers who produce a generic of a reference-listed drug that has already completed the NDA process. *See* 57 Fed. Reg. 17950, 17951 (describing Hatch-Waxman Act). ANDA drugs must (1) be "the same as" a reference-listed drug that was already approved by the FDA with respect to active ingredients, route of administration, dosage form, strength and conditions of use recommended in the labeling; or (2) include changes from a reference-listed drug if the FDA has approved a petition from a prospective applicant permitting the submission of an ANDA for the changed drug product. *See* 21 U.S.C. § 355(j). One of the benefits to manufacturers who opt for the ANDA procedure is that they are required only to conduct "bioequivalency" studies that establish that the generic and the reference-listed drug are pharmaceutically equivalent; the ANDA procedure does not require the

safety and effectiveness tests that are necessary under the NDA procedure. The underlying presumption is that so long as the drug is shown to be pharmaceutically equivalent to an existing reference-listed drug, and so long as it is used in the same manner as the reference-listed drug, FDA approval can be assumed without requiring duplication of previously-performed studies.

As part of the ANDA application, a manufacturer must show that the labeling of the generic and reference-listed drug will be the same. *See* § 355(j)(2)(A)(v) (requiring "information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug . . ."). Teva argues that it is therefore obligated under federal law to assure that its labeling remains identical to that of the reference-listed drug, no matter the accuracy of that labeling, and no matter if Teva later learns of evidence questioning the efficacy of the drug. Teva also emphasizes that 21 C.F.R. § 314.150 permits the FDA to withdraw an ANDA approval after a hearing pursuant to § 314.200, if the FDA finds "[t]hat the labeling for the drug product that is the subject of the abbreviated new drug application is no longer consistent with that for the listed drug referred to in the abbreviated new drug application, except for differences approved in the abbreviated new drug application . . . ." § 314.150(b)(10). However, Teva does not point to any instances where the FDA has invoked this procedure to withdraw an ANDA because a generic drug manufacturer added or strengthened warnings.

The core of Teva's argument—especially after the Supreme Court's decision in *Levine*—is whether the CBE provisions that permit manufacturers to add additional warnings to their labels without prior FDA approval is exclusively available to name-brand manufacturers, or if generic manufacturers, may also utilize this process. If generic manufacturers can utilize the CBE, then the logic of *Levine* is directly applicable.

The CBE regulations appear at 21 C.F.R. § 314.70(c)(6)(iii), which is located in Subpart B of Part 314. Subpart B is generally applicable to *new* applications, whereas, Subpart C is applicable to *generic* (or, "abbreviated") applications. *Compare* 314 C.F.R. Subpart B (titled "Applications") *with* Subpart C (titled "Abbreviated Applications"). However, section 314.97, which is located within Subpart C, states that "The applicant shall comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application." § 314.97. In other words, the regulations affecting generic drug applications state explicitly that the CBE provisions apply to generic drug manufacturers just as they do to name-brand manufacturers.

Notwithstanding this clear regulatory language, Teva points to statements proffered by the FDA itself, which state that generic manufacturers are *prohibited* from utilizing the CBE. In particular, on January 18, 2008, the FDA published a proposed new rule in the federal register, and included a lengthy preamble. Within this preamble, the FDA inserted a footnote which states that "CBE changes are not available for generic drugs approved under an abbreviated new drug application under 21 U.S.C. 355(j). To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug. *See* 21 CFR 314.150(b)(10);[5] *see also* 57 FR 17950, 17953, and 17961.[6]" Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2849 n.1 (proposed Jan. 16, 2008) ("2008 preamble") (explanatory footnotes added).

[5] This provision relates to the authority of the FDA to withdraw an ANDA approval for failure to comply with the labeling requirements of the reference-listed drug.

[6] These references refer to the requirement that an ANDA applicant must provide the FDA with an identical label to the reference-listed drug when seeking ANDA approval.

Given the conflict between the regulations and the FDA's preamble, the court must consider what deference the FDA's preamble deserves. This issue was considered in *Levine*, where the Court examined an FDA preamble from 2006 in which "the FDA declared that the FDCA labeling requirements establish 'both a "floor" and a "ceiling,"' so that 'FDA approval of labeling . . . preempts conflicting or contrary State law.'" *Id.* at *10. The Court found that *Skidmore* deference is applicable, given that the preamble had not been subjected to notice-and-comment. *Id.* at *10 (citing,*Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). As the Court explained, agencies

> do have a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress." The weight we accord the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness.

Id. (citations omitted). However, the Court then observed that the 2006 preamble contradicted every statement on the issue that came from Congress, and concluded that the 2006 preamble did not deserve any deference because the preamble did *not* explain its reasoning and contradicted the relevant legislative history. *Id.*

This court is aware that, as to generic drugs, the district courts to have considered the issue are divided. *See, e.g.*, *Mensing v. Wyeth*, 562 F. Supp. 2d 1056 (D. Minn. 2008) (finding state law preempted); *Kellogg v. Wyeth*, No. 2:07-cv-82, 2008 WL 5272715 (D. Vt. Dec. 17, 2008) (finding no preemption); *Tucker v. SmithKline Beecham Corp.*, No. 1:04-cv-1748-DFH-WTL, 2008 WL 2788505 (S.D. Ind. July 18, 2008). Given the sweeping language and overall conclusions of the Supreme Court in *Levine*, this court concludes that such claims should not be preempted as a matter of law.

The court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."

Levine, 2009 WL 529172 at *5. As explained in *Levine*, each drug manufacturer under the FDA "bears responsibility for the content of its label at all times." *Id.* at *8. The Court evaluated the history of the FDCA and found that Congress "determined that widely available state rights of action provide[] appropriate relief for injured consumers." *Id.* at *10. Congress was aware of state tort remedies, and chose not to foreclose them. *Id.* "Its silence on the issue, coupled with its certain awareness of the procedure of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.*

There is no reason to conclude that Congress felt differently about generic drugs. Although it is clear that the Hatch-Waxman Amendment was devised to allow generic drug manufacturers to get their drugs to market both cheaply and quickly, this purpose was to be achieved by permitting manufacturers to forego duplicative clinical trials. It was *not* to be achieved by permitting manufacturers to engage in negligent activities. *See Kellogg*, 2008 WL 5272715 at *8 (citing *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 191 (2d Cir. 2006)). Although Congress intended for ANDA applicants to submit identical labeling to the FDA when seeking ANDA approval—*see* 21 U.S.C. § 355(j)(2)(A)(v)—the statute is silent as to the manufacturer's obligation after the ANDA is granted. But 21 C.F.R. § 314.97 is not silent—it states that generic drug manufacturers are obligated to comply with the same CBE provisions as brand-listed manufacturers are.

Nor, from this history and the Court's analysis in *Levine*, can the court agree that permitting state-law tort actions would necessarily frustrate the purpose of Congress in passing the Hatch-Waxman Amendment. The underlying purpose of the FDCA is not making sure that drugs can be quickly and cheaply brought to market, but rather to assure that the drugs are safe when they are brought to market. *See Levine*, 2009 WL 529172 at *6–*8. Congress has indicated that state tort-law is an integral part of this process; "[f]ailure-to-warn actions, in particular, lend force to the

FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at *12.

The FDA's statements in the 2008 preamble do not provide a basis for contradicting this underlying Congressional understanding of the FDCA. The footnote merely reiterates what Congress itself provided—that during the application process, the ANDA must be identical to the reference-listed drug. *See supra* at n.6 and related text. While it is likely that a generic manufacturer may be spared any risk of negligence liability *during the application process*,[7] there is no basis to conclude that this protection against negligence suits continues after the ANDA is approved.

At this stage of the litigation, the court is unwilling to conclude that Stacel's claims are preempted by federal law.

CONCLUSION

Teva's motion to dismiss is denied.

ENTER:

/s/
JOAN B. GOTTSCHALL
United States District Judge

DATED: March 16, 2009

[7] This is likely true given that Congress provided that the ANDA application itself must be identical to the reference-listed drug. 21 U.S.C. § 355(j)(2)(A)(v).